



UNITED STATES ENVIRONMENTAL PROTECTION  
AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**MEMORANDUM**

**June 12, 2020**

**Subject:** Ecological Risk Assessment for Federally Listed Species for Cuprous Iodide

PC Code: 108301	DP Barcode(s)/No(s): 455276
Decision No(s): 557596	Regulatory Action: Product Registration – Section 3
Risk Assessment Type: Single Chemical	Case No(s): N/A

**To:** Jacqueline Hardy, Product Manager  
Regulatory Management Branch II  
Antimicrobials Division (AD) (7510P)

**From:** Melissa Panger, Ph.D., Branch Chief  
Risk Assessment Science Support Branch (RASSB)  
Antimicrobials Division (AD) (7510P)

**Through:** Diana Hsieh, Ecological Risk Assessment Process Leader  
Laura Parsons, Associate Branch Chief  
Risk Assessment Science Support Branch (RASSB)  
Antimicrobials Division (AD) (7510P)

*D.Hsieh*

*Laura Parsons*

**Background:**

This memorandum includes the Antimicrobial Division (AD), Risk Assessment and Science Support Branch (RASSB)'s ecological risk assessment for listed species (those federally listed as endangered or threatened) and their designated critical habitats for cuprous iodide (PC Code 108301). Cuprous iodide is an antimicrobial pesticide. AD assessed the currently registered uses for which cuprous iodide may be sold and distributed based on an amendment request to revise the Cupron Cuprous Iodide Masterbatch (20% cuprous iodide; EPA Reg. No. 84542-9) label. This is referred to as the proposed Revised Label for this memorandum.

The uses of cuprous iodide on the proposed Revised Label are for material preservatives in manufactured products (*i.e.*, fibers, plastics and films). To produce the treated fibers, plastics and films, a masterbatch (*i.e.*, the manufacturing product which is formulated as solid pellets of polymer/cuprous iodide blend) is mixed with a compatible polymer used to create fibers, plastics, or films. The treated materials (*i.e.*, treated fibers, plastics, and films) do not exceed a cuprous iodide concentration of greater than 5%, which is spread uniformly throughout the treated material. According to the proposed Revised Label, cuprous iodide is used to suppress the growth of algae, mold, mildew, fungi and bacteria which may cause unpleasant odors,

discoloration, staining, deterioration or corrosion of articles produced from the treated material. The proposed Revised Label includes only the following uses:

**Fibers: The final article is to contain from 0.2% to 25% Cupron Cuprous Iodide Masterbatch by weight. Final concentration of 0.04 to 5% Active.** Fiberfill for quilts and pillows, vacuum cleaner bags, sleeping bags, brush bristles, air and dust filters, book covers, carpets, rugs, mats, carpet underlay, carpet backing, broadloom and tile carpeting, conveyor belts that do not come in contact with any type of food, automotive and truck upholstery, automotive and truck carpeting and interior liners, shoes, gloves and helmets, sails, ropes, canvas, ducking, awnings, and umbrellas.

**Plastics and films: The final article is to contain from 0.2% to 25% Cupron Cuprous Iodide Masterbatch by weight. Final concentration of 0.04 to 5% Active:** Automotive and vehicular parts, brush handles, building materials and components (excluding shingles), wood composites, non-food contact plastic composites, conveyor belts that do not come in contact with any type of food, floor covering, flooring, footwear including boots, furniture, gaskets, glazing for cement tile and for toilets, indoor furniture, insulation for wire and cable, insulators, kitchen and bathroom hardware, plumbing supplies and fixtures including sinks, indoor sports equipment, tape, tiles, tubing, vacuum cleaner bags, wallboard, walls, waste containers, personal hygiene devices such as combs, brushes, and hairclips.

**Do not use as a coating, film or laminate on any other product than those listed on this label.**

A determination of risks depends on the potential environmental exposures reasonably expected to occur and hazards (*i.e.*, toxicity). Risk is only expected if exposures reach levels high enough to cause adverse effects. The potential exposures reasonably expected to occur are discussed in the section below, followed by a discussion of ecotoxicity.

### **Exposure:**

Articles treated with cuprous iodide are treated using a masterbatch manufacturing product. The cuprous iodide is expected to be tightly bound in most treated matrices (USEPA, 2015) (see **APPENDIX A**) because it exists in the form of particles embedded within articles made of plastics, films and fibers. Because the particles are embedded throughout the polymer matrix rather than sitting on the surface, the potential environmental exposure reasonably expected to occur to cuprous iodide from these uses is extremely limited and not reasonably expected to reach concentrations high enough to cause any adverse effects to non-target species. Exposure to terrestrial species from the use of this product is not expected because the only potential exposures to outdoor habitats would be the result of leaching from a treated article during exposure to water. Regarding aquatic exposures, there are two potential routes of exposure: leaching from treated articles found outdoors and down-the-drain discharges via leaching from treated fibers during fabric washing at industrial facilities, commercial establishments, and residences (USEPA, 2015). Because cuprous iodide will dissociate in water, any cuprous iodide

that may reach aquatic habitats is expected to be present predominantly in the form of copper and iodine ions (USEPA, 2015).

Of the two potential routes of exposure, leaching is expected to be higher during fabric washing, owing to the agitation and surfactants, than through any other route. Most of the treated materials specified on the proposed Revised Label would be found in building or vehicle interiors and/or would not be washed in washing machines (*e.g.*, automotive upholstery, air filters); therefore, EPA does not expect any potential copper and iodine ions to leach into outdoor habitats from these treated articles. For the treated products listed on the proposed Revised Label that may be found outdoors (*e.g.*, awnings, sails, building materials), or those that have the potential to be washed in washing machines (*e.g.*, sleeping bags and pillows), the potential for environmental exposures is reasonably expected to be below concentrations where effects would occur. This is based on several factors, such as a low leach rate from the polymer matrix (for outdoor and down-the-drain uses), removal through wastewater treatment plants, and expected infrequent washing frequencies (specifically for the down-the-drain uses). These factors are discussed further below.

Based on the available information, the leaching rates of copper and iodine ions from treated polymer fibers is low (MRID 49485901). The leaching rate (after soaking for 60 minutes in water) is up to 1.7 µg/g of fabric (which equals 0.00017% of fabric weight) for copper and 8.3 µg/g of fabric (which equals 0.00083% of fabric weight) for iodide. Additionally, leaching rates for copper and iodine ions are similar across woven and non-woven textiles indicating that the leaching rates are not affected by the nature of the treated fabrics. Furthermore, based on information from EPA's Office of Water, the level of exposure to cuprous iodide from down-the-drain uses is reduced even further before reaching any aquatic habitats, because some portion of the copper and iodine ions that have leached from treated materials during washing (that may percolate from the treated fibers and may leach from treated materials during the washing process) are likely to be removed through the wastewater treatment process. For copper ions, the percent removal during wastewater treatment is 84.2% based on available data reported by the EPA's Office of Water (USEPA, 2003). EPA does not have data for the percent removal of iodine ions, although iodine is less toxic to aquatic organisms than copper (see below). Additionally, the types of treated articles on the proposed Revised Label that may be washed in washing machines are expected to be washed infrequently, if at all (*e.g.*, sleeping bags and pillows).

### **Ecotoxicity:**

As noted above, because cuprous iodide dissociates in water, any cuprous iodide that may reach aquatic habitats is expected to be present predominantly in the form of copper and iodine ions. Based on the available ecotoxicity data, copper (ions), which is classified on an acute basis as very highly toxic to aquatic animals (both vertebrates and invertebrates) and moderately toxic to birds, is more toxic than cuprous iodide and iodine (ions) to aquatic and terrestrial organisms (see **APPENDIX B**). In addition to reviewing the available ecotoxicity data, a search of EPA's

Incident Data System (IDS) was conducted on December 5, 2019 and no ecological incidents involving the use of cuprous iodide<sup>1</sup> were located.

### **Risk Conclusions:**

Although cuprous iodide, copper (ions), and iodine (ions) do show toxicity to non-target organisms, the uses on the proposed Revised Label are not reasonably expected to result in potential exposures to terrestrial and aquatic organisms (including listed species and their designated critical habitat) at levels that would result in a discernible effect.

Exposure to terrestrial species from the use of this pesticide product is not expected because the cuprous iodide bound within the treated materials is not accessible (the only potential exposures to outdoor habitats would be the result of leaching after exposure to water from the limited amount of copper and iodine ions that migrate to the surface of a treated material). Without exposure, there would not be a discernible effect to terrestrial species from the uses as material preservatives in manufactured products (*i.e.*, fibers, plastics, and films) permitted by the proposed Revised Label.

Any potential aquatic exposures from the uses on the proposed Revised Label are not reasonably expected to occur at levels that would result in a discernible effect. Most of the treated materials in the list of uses on the proposed Revised Label represent indoor uses (*i.e.*, inside buildings or vehicles) and/or are not washed in washing machines. For the treated items that can be found outdoors, cuprous iodide is expected to be tightly bound in the polymer matrices, with very low leaching rates no greater than 1.7 micrograms of copper per gram of treated material per hour of immersion and 8.3 micrograms of iodine per gram of treated material per hour of immersion. For those treated items that could be washed, there is a potential for down-the-drain discharges via leaching from treated fibers during fabric washing at industrial facilities, commercial establishments, and residences. However, the types of treated fabrics that could be washed in washing machines are expected to be washed infrequently, if at all (*e.g.*, sleeping bags, pillows), and would be diluted by water from other laundry (and other water sources) in a water-treatment area before reaching any aquatic habitat. Furthermore, there would be significant removal through wastewater treatment of any copper and iodine ions that may have leached from the washing process (*e.g.*, 84.2% removal for copper ions, the most toxic of the cuprous iodide residues) before the wash water would reach an aquatic habitat.

Therefore, there is no reasonable expectation of risks (*i.e.*, direct adverse effects) to non-target organisms due to the limited potential for exposure in terrestrial and aquatic environments. Because direct adverse effects are not expected for any non-target organism (including birds, reptiles, amphibians, mammals, fish, aquatic invertebrates, aquatic plants, terrestrial plants, and terrestrial invertebrates), EPA is making a No Effects (NE) determination for all federally listed threatened or endangered species for the uses of cuprous iodide identified on the proposed Revised Label. Additionally, because there are no effects expected for any terrestrial or aquatic

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<sup>1</sup> There are ecological incidents involving copper reported in IDS, but none are related to the use of cuprous iodide.

species from the uses on the proposed Revised Label, EPA is also making a NE determination for designated critical habitats.

**References:**

MRID 49485901. Availability of Iodide and cuprous ions from CuI Impregnated Textiles, Cupron, Inc., Richmond, VA. Timothy Klock, 2014.

USEPA, 2003. Development Document for the Final Effluent Limitations Guidelines and Standards for Metal Products and Machinery Point Source Category. United States Environmental Protection Agency, Office of Water. February 2003. Washington, DC.

USEPA, 2015. Human Health and Ecological Risk Assessment for Cuprous Iodide. United States Environmental Protection Agency, Antimicrobials Division, Risk Assessment and Science Support Branch. Washington, DC. August 25, 2015.

## APPENDIX A: Release of Cuprous Iodide from Treated Articles<sup>2</sup>

Cuprous iodide, as it results from use of the Cupron Cuprous Iodide Masterbatch product, is in the form of particles embedded within plastics, polymer fibers and textiles. As the particles are embedded and distributed evenly within the polymer matrix rather than sitting on the surface, their exposure to the environment is minimal. The polymer physically prevents the cuprous iodide particles from transporting to the surface. This limits environmental exposures to 1) cuprous iodide particles that may be on the polymer surface, and 2) copper and iodide ions which may migrate to the surface and be solvated.

The number of particles found on the surface of any treated article is anticipated to be minimal due to the low percentage of cuprous iodide in the finished product (0.04 to 5%) and its dispersal throughout the finished product (further reducing the quantity at the surface), ultimately limiting the amount of cuprous iodide available to be released from treated articles. Additionally, cuprous iodide has very low solubility, and the copper ion and iodine ion concentrations in water (from the use of cuprous iodide) would be below the solubility limit of cuprous iodide. There are some discrepancies in the literature, as the solubility values for cuprous iodide are commonly misreported. The  $K_{sp}$  (solubility product) at 20 °C (293 K) was determined to be  $5.06 \times 10^{-12}$  mol/L, while the  $K_{so}$  (solubility product at zero ionic strength) at 25 °C (298.15 K) was determined to be  $1.2 (\pm 0.1) \times 10^{-12}$  mol/L (Fritz, 1991). The calculated solubility (mg/L) depends on whether the  $K_{sp}$  or  $K_{so}$  is used, with calculated solubilities of 0.42 mg/L based on the  $K_{sp}$  and 0.21 mg/L based on the  $K_{so}$ . Confusion stems from many texts reporting the  $K_{sp}$  as  $1.2 (\pm 0.1) \times 10^{-12}$  mol/L but giving 0.42 mg/L as the solubility. Regardless of which values are used, both 0.21 and 0.42 mg/L are extremely low solubilities, and the cuprous iodide itself is not expected to dissolve to any significant degree in surrounding waters.

Cuprous iodide is also thermally stable, with a melting point of 591 °C (CRC, 2020). This temperature is likely to be reached and exceeded only during incineration of the article, which is beyond the scope of EPA's effects determination assessments. However, it should be noted that cuprous iodide does not break down into individual ions at the melting temperature because of its thermal stability. Even in higher temperatures, the number of ions being generated from the breakdown of cuprous iodide is expected to remain relatively constant (*e.g.*, more ions are not expected to be generated under high-temperature conditions). Furthermore, the breakdown is expected to remain relatively constant under variable environmental conditions. Therefore, differences in temperature in the environment will not affect the breakdown.

The parent cuprous iodide particles are physically prevented from migrating out of the polymer matrix, have extremely low solubility, and are thermally stable. As a result, it is assumed that exposure will be primarily to degradate copper and iodide ions that migrate to the surface of the polymer, rather than to the parent cuprous iodide. Based on the leaching study discussed below, migration is not a fast process; therefore, ions which are generated from the slowly degrading

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<sup>2</sup> This appendix was written by Andrew Byro, Ph.D. (Chemist); Sophia Hu (Chemist); Danielle McShan, Ph.D. (Chemist); and James Breithaupt (Agronomist). Risk Assessment and Science Support Branch, Antimicrobials Division, Office of Pesticide Programs.

parent will in turn be slowly released. Given the stability of the parent and the slow release of the ions, exposure is expected to be minimal.

The Agency received MRID 49485901 which supports this position. This study found that the leaching rates of copper and iodide ions from treated fibers were low and similar across woven and non-woven textiles, indicating that the leaching rates are not affected by the nature of the treated fabrics. The leaching rate (after soaking for 60 minutes in water) for copper ion was 0.00017% of fabric weight (0.002-0.003% of parent cuprous iodide), and 0.00083% of fabric weight (0.016-0.0167% cuprous iodide) for iodide ion.

### **References:**

CRC Handbook of Chemistry and Physics. Cleveland, Ohio: CRC Press. <http://hbcponline.com/>, retrieved 02/19/2020

Fritz, J. International Union of Pure and Applied Chemistry, Solubility Data Series, Volume 65: Copper(I) Halides and Pseudohalides. 1991, 195.

MRID 49485901. Klock, T. (2014) Availability of Iodide and Cuprous Ions from Cuprous Iodide Impregnated Textiles. Project Number: 28/14/2, 2014/09/09/010. Unpublished study prepared by Microbac Laboratories, Inc. 54p.

## APPENDIX B: Ecotoxicity Endpoints for Cuprous iodide, Copper, and Iodine

Provided below are the ecotoxicity endpoints for cuprous iodide (**Table 1**), copper (**Table 2**) and iodine (**Table 3**) as reported in the Office of Pesticide's (OPP) 2015 risk assessment for cuprous iodide (USEPA, 2015)<sup>3</sup>. Copper is regulated under the Federal Insecticide Fungicide Rodenticide Act (FIFRA), Clean Water Act (CWA), and the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). At the time of the last OPP cuprous iodide assessment (USEPA, 2015), water, sediment, and soil criteria had been updated by EPA's Office of Water (OW) and Office of Solid Waste and Emergency Response (OSWER), based primarily on extensive review and analysis of open literature. In the 2015 assessment, for aquatic animals, OPP reported the Genus Mean Acute Values (GMAVs) for acute risk and acute-to-chronic ratios (for chronic risk) calculated by OW, to be used to calculate site-specific endpoints using the Biotic Ligand Model (BLM). The BLM, a combined speciation and toxicity model, allows calculation of toxicity values based on site specific water chemistry. The OW endpoints used in the 2015 assessment are reported below for copper (see **Table 2**).

**TABLE 1: Ecotoxicity Endpoints for Cuprous Iodide**

TAXON	ENDPOINT	TOXICITY CATEGORY	MRID
Birds (Northern Bobwhite Quail)	LD <sub>50</sub> = 1,416 mg a.i./kg-bw (acute study)	Slightly Toxic	49485701
Freshwater fish (Fathead minnow)	LC <sub>50</sub> > 251 µg a.i./L (acute study)	N/A <sup>1</sup> (since the endpoint is non-definitive)	49510802
Freshwater invertebrate ( <i>Daphnia</i> )	EC <sub>50</sub> = 88 µg a.i./L (acute study)	Very Highly Toxic	49510801
Algae (Green algae)	EC <sub>50</sub> = 158 µg a.i./L NOAEC = 53 µg a.i./L	N/A	49485801

<sup>1</sup> N/A = not applicable

**TABLE 2: Ecotoxicity Endpoints for Copper**

TAXON	ENDPOINT <sup>1</sup>	TOXICITY CATEGORY	MRID
Freshwater fish (Salmonids)	GMAV <sup>2</sup> = 31.4 µg a.i./L (acute)	Very Highly Toxic	N/A <sup>3</sup>
Estuarine/Marine fish	GMAV = 12.7 µg a.i./L (acute)	Very Highly Toxic	N/A
Freshwater invertebrate ( <i>Daphnia</i> )	GMAV = 4.1 µg a.i./L (acute)	Very Highly Toxic	N/A
Estuarine/Marine Invertebrate (Mussel)	GMAV = 11.5 µg a.i./L (acute)	Very Highly Toxic	N/A
Vascular aquatic plant (Duckweed)	EC <sub>50</sub> = 2,300 µg a.i./L NOAEC = 100 µg a.i./L	N/A	43363604
Non-vascular aquatic plant	EC <sub>50</sub> = 3.1 µg a.i./L NOAEC = 2 µg a.i./L	N/A	43363603

<sup>3</sup> USEPA, 2015. Human Health and Ecological Risk Assessment for Cuprous Iodide. United States Environmental Protection Agency, Antimicrobials Division, Risk Assessment and Science Support Branch. Washington, DC. August 24, 2015.

<sup>1</sup> The endpoints provided for aquatic animals are for acute exposures; for chronic exposure endpoints, an acute-to-chronic ratio of 3.2 would be applied to the Biotic Ligand Model- (BLM) derived site-specific acute toxicity values.

<sup>2</sup> GMAV = Genus Mean Acute Value; to get a site-specific endpoint, this value is used in the BLM model.

<sup>3</sup> N/A = not applicable

**TABLE 3: Ecotoxicity Endpoints for Iodine**

TAXON	ENDPOINT	TOXICITY CATEGORY	MRID
Birds (Northern Bobwhite Quail)	LD <sub>50</sub> >2,000 mg a.i./kg-bw (acute study)	Practically Non-toxic	43138401
Freshwater fish (Bluegill)	LC <sub>50</sub> = 610 µg a.i./L (acute study)	Highly Toxic	43044501
Freshwater invertebrate ( <i>Daphnia</i> )	EC <sub>50</sub> = 330 µg a.i./L (acute study)	Highly Toxic	42961001